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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/284,233 07/28/99 MEYER

T P564-9008

EXAMINER

HM22/0321

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DEVI, S

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

03/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/284,233

Applicant(s)
Meyer et al.

Examiner
S. Devi, Ph.D.

Group Art Unit
1641

☒ Responsive to communication(s) filed on 11/23/99.

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-16 ~~is~~ are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-16 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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Lack of Unity of Invention

- 1) Claims 1-16 are under prosecution.
- 2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3) Restriction to one of the following inventions is required under PCT Rule 13.1 and 13.2:
 - I. Claims 1-15, drawn to a pharmaceutical composition comprising a living recombinant attenuated bacterium vaccine which comprises heterologous nucleic acid molecule encoding a *Helicobacter* antigen and a method for the preparation of the pharmaceutical composition, classified in class 424, subclass 93.2.
 - II. Claim 16, drawn to a method for identifying *Helicobacter* antigens that raise a protective immune response in a mammalian host, classified in class 435, subclass 69.3.
- 4) Inventions I and II lack unity of invention due to the absence of a special technical feature. The special technical feature of Invention I is a pharmaceutical composition comprising a living recombinant attenuated bacterium vaccine which comprises heterologous nucleic acid molecule encoding a *Helicobacter* antigen and a method for the preparation of the pharmaceutical composition. The special technical feature of Invention II is a method for identifying *Helicobacter* antigens that raise a protective immune response in a mammalian host by providing an expression gene bank of *Helicobacter*. Individually, the product and the process of preparing the product of invention I are a permitted combination of categories under PCT Rule 13.2. However, the special technical features of invention I and invention II are not linked, and

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therefore the two inventions lack unity. The product of invention I is not required to practice the method of invention II. Furthermore, the inventions have acquired a separate status in the art as shown by their different classifications/subclassifications and divergent subject matter.

5) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

6) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

7) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SD
S. Devi
Patent Examiner
March 2000



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER: Dr. S. Devi

ART UNIT: 1641

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 305-3704

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY
FOR RESPONSES TO RESTRICTIONS.**

COMMENTS: _____

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